

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION)
and GENEVANT SCIENCES GmbH,)

Plaintiffs,)

v.)

MODERNA, INC. and MODERNATX, INC.)

Defendants.)

MODERNA, INC. and MODERNATX, INC.,)

Counterclaim-Plaintiffs,)

v.)

ARBUTUS BIOPHARMA CORPORATION)
and GENEVANT SCIENCES GmbH,)

Counterclaim-Defendants.)

C.A. No. 22-252 (MSG)

**LETTER TO THE HONORABLE MITCHELL S. GOLDBERG IN OPPOSITION TO
PLAINTIFFS' MOTION TO COMPEL SAMPLES**

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Dear Judge Goldberg:

Plaintiffs filed their Motion (D.I. 161) because the extensive lipid content data Moderna produced shows its COVID-19 vaccine does not infringe. To try to keep their case alive, Plaintiffs now seek unprecedented numbers of samples to run unidentified, unconventional tests to try to obtain contradictory results, including by testing many expired samples that Plaintiffs know are not representative of the unexpired product. Although Plaintiffs have all information necessary to assess infringement—including certificates of analysis (“CoAs”) reporting lipid content and underlying data for every accused batch, Moderna has further agreed to provide a substantial number of samples as discussed below. Plaintiffs’ request for even more drug product samples from 1000+ batches and samples of [REDACTED]—defy the bounds of proportionality.

The unreasonable scope of these requests, compounded by Plaintiffs’ other burdensome discovery demands have, as forecasted, put Moderna in a position where an extension to the schedule is necessary. Moderna wishes to discuss such an extension at any hearing on this dispute.

I. Drug Product Samples (RFP No. 97)

Moderna is producing lipid content data for each accused batch: Plaintiffs filed this suit asserting infringement of claims requiring specific lipid molar ratios and then pressed Moderna for its regulatory filings, arguing that “testing Moderna has done . . . related to the lipid molar ratio . . . is highly relevant.” Ex. 1 at 2; Ex. 2. Moderna promptly produced its filings, which included lipid content testing that confirm Moderna’s vaccine lacks the claimed lipid ratios. Ex. 4 at 14–28. Moderna is also complying with Plaintiffs’ further requests to produce CoAs with lipid content results for every accused batch¹ and underlying raw data. Ex. 5 at 3–4; Ex. 6 at 1–2.

Unhappy with the data they received, Plaintiffs pivoted to argue the FDA regulatory filings and CoAs—made under penalty of criminal prosecution per 18 U.S.C.A. § 1001 and § 10.20(i)—“largely comprise information *irrelevant* to infringement.” Mot. at 2. Plaintiffs now contend that infringement turns on lipid content of *individual* LNPs rather than “aggregate” formulations. Mot. at 2–3. Plaintiffs’ new contention is baseless. HPLC—Moderna’s FDA-approved method to measure aggregate lipid content—is standard and is also used by Plaintiffs and the inventors of the asserted patents.² Ex. 9, ¶ 56; Ex. 10; Ex. 11 at -942 and -950; Exs. 12 & 13 at 6–7; Ex. 14, ¶¶ 21, 31–32. In fact, Plaintiffs’ complaint and infringement contentions rely *solely* on aggregate lipid content. Ex. 15 at 2-10; D.I. 1, ¶ 45. Confirming the speculative nature of this new contention, Moderna’s expert, Professor Byrn, explains he is unaware of *any* method for isolating an individual LNP, let alone determining its lipid content. Ex. 14, ¶¶ 49–51. Despite having a set of Moderna’s samples for over 8 months (Ex. 16), Plaintiffs presented no evidence refuting the HPLC results Moderna submitted to the FDA. *See* Ex. 17, *Par Pharm., Inc. v. Hospira, Inc.*, C.A. No.

¹ Moderna agrees to produce samples for *accused* batches, and does not agree to Plaintiffs’ recent attempt to seek discovery into batches not made, imported, or sold in the U.S. *See, e.g. Invensas*, D.I. 53 (Ex. 3) (limiting production of samples of product defendant “‘makes, uses, offers to sell, or sells . . . within the United States or imports into the United States.’” 35 U.S.C. § 271”).

² Although the asserted patents do not describe a method for measuring lipid content, the inventors’ lab notebooks show they also used HPLC. Ex. 7 at 559; Ex. 8 at 5; Ex. 14, ¶¶ 36–37.

17-944-JFB-SRF, D.I. 63, at *5,6 (D. Del. May 14, 2018) (denying motion to compel expired samples without prejudice where Hospira produced ANDA).

Moderna’s compromise properly balances need and burden: Despite Plaintiffs having all the information they need, in the spirit of compromise, Moderna offered to produce a reasonable number of samples, *i.e.*, 3 drug product vials^{3,4} from one batch per unique part number (*i.e.*, every version of its COVID-19 vaccine).⁵ The accused batches fall into three categories: (1) unexpired and (2) up to 1 year past expiry, for both of which Moderna must keep regulatory retains (Ex. 18, ¶¶ 3–4), and (3) more than 1 year past expiry. Moderna would pull such samples from available inventory and/or regulatory retains for (1) and available regulatory retains for (2)/(3). To further narrow the dispute, Moderna is producing samples from 400+ batches from (3) that, as Plaintiffs knew, were being transferred from a third-party and thus, more accessible to produce. Ex. 19 at 1.

Plaintiffs’ request is the epitome of undue burden: Plaintiffs baselessly claim “[i]t is not burdensome for Moderna to produce samples.” D.I. 161 at 3. This could not be further from the truth. Production of FDA-regulated drug product stored at [REDACTED] is an arduous, manual exercise of developing and documenting a complex process, including checking various electronic systems, confirming inventory in [REDACTED] freezers (which Moderna’s personnel must enter in pairs and remain in for mere minutes at a time for safety), and procuring and preparing specific packaging to control temperature during shipment. Ex. 20 at 4; Ex. 21, ¶¶ 12-13; Ex. 18, ¶ 2. Even for the 400+ batches Moderna is pulling samples from, a team of 15+ Moderna employees has been working for weeks to make the production possible. Ex. 21, ¶¶ 8–10. That Moderna is undertaking this effort for those uniquely situated batches does not lessen the burden for the remaining 1000+ batches, particularly where Plaintiffs have not even committed to testing any, let alone all samples. Ex. 22 at 2. Without any credible explanation as to why samples from every batch are needed, particularly where many are expired, Plaintiffs have failed to show the extreme “burden or expense of the proposed discovery outweighs its likely benefit,” warranting denial of its motion. Fed. R. Civ. P. 26(b)(1); *Rembrandt Diagnostics, LP v. Innovacon, Inc.*, 2017 WL 4391707, at *3 (S.D. Cal. Oct. 3, 2017).

While Moderna’s proposal is grounded in precedent—*see, e.g., Everlight*, 2013 WL 6713789, at *2 (ordering production of one sample per part number); *3Com*, 2007 WL 949596, at *2 (ordering production of each ‘version’)—Plaintiffs cite no cases ordering production of samples of **every batch**, let alone where FDA-approved testing for the claimed characteristics was produced for all batches. *See Vitamins Online*, 2016 WL1305144, at *1 (ordering production from 5 lots); *P&G*, 2013 WL 152801, at *6 (ordering production of “representative samples”); *Integra*, 2016 WL 675553, at *1 (ordering production of “[f]ive samples of each [] Product,” not each batch). Moderna’s proposal is also particularly reasonable in light of the material Moderna has already produced and Plaintiffs’ failure to articulate relevance “sufficient to justify production for each [batch] and overcome the burdensome nature of the request.” *Rembrandt*, at *3, 5–6. Unlike *Prism* (Mot. at 2), where Defendant “fail[ed] to produce **any** documents,” Moderna has produced hundreds of thousands of pages relevant to non-infringement. *Prism*, 2015 WL 5883764, at *3

³ For batches manufactured as single-dose syringes, Moderna will produce equivalent volume.

⁴ Plaintiffs’ motion did not specify a volume, but previously demanded 100 mg of lipid content per batch. Ex. 5 to Mot. at 2. This far exceeds proportionality. Ex. 14, ¶¶ 23, 38–48. An HPLC/UHPLC method used by Plaintiffs requires 3 µg; 3 vials allows up to 6,000+ tests. *Id.* ¶ 47.

⁵ “Part numbers” identify product based on formulation and manufacturing process.

(deciding motion to strike expert theories, with no mention of samples); *see also Invensas* (Ex. 3 at 23, 26) (ordering production of “samples of each of its [] products” where documents lacked “relevant information . . . to evaluate infringement.”). Moderna’s proposal is more than sufficient.

Plaintiffs’ representativeness proposal is unreasonable: Plaintiffs argue Moderna’s proposal is “untenable” because Moderna refuses to concede infringement of batches from which no samples are produced. But Plaintiffs’ proposal was a non-starter: Plaintiffs wanted to select 100 batches from which samples would be produced, and have Moderna “stipulate[] that a finding of infringement as to *one or more* of the Accused Batches will constitute a finding that *all* of the Accused Batches infringe.” Ex. 23. This would allow Plaintiffs to selectively produce results from a single batch, while preventing Moderna from contesting infringement of *any other* batch (even batches it produced samples from). Again, this is not a scenario where the lipid content is unknown; Moderna is producing data for *all* batches, Plaintiffs simply do not like the results. *Wonderland*, 2021 WL 2315191, at *2 (defendant had “no design documents showing the structure of some of the accused products”). Moderna also cannot agree that each sample is representative as many are expired. [REDACTED]

Plaintiffs identify *no* precedent for such limits on Moderna’s ability to contest infringement, which remains Plaintiffs’ burden. For example, in *Apple* (Mot. at 2), the court suggested the defendant “negotiate a stipulation that its production [of *documents*] adequately represents . . . the entire set of accused products,” rather than samples. 2012 WL 1511901, at *6. Matters of testing methodology and representativeness should be left to the experts.

II. [REDACTED] Samples & Raw Data (RFP Nos. 108, 174)

Unsatisfied that Moderna’s vaccine does not infringe, [REDACTED]

[REDACTED] *Medtronic*, cited by Plaintiffs, confirms they have all they need: there, the court ordered production of “manufacturing process *documents*” which Plaintiffs already have. 2004 WL 115594, at *3 (Mot. at 3).

Moderna respectfully requests that the Court deny Plaintiffs’ Motion to Compel.

⁶ Although Plaintiffs do not specify the “raw data” that they seek, it underlies the same HPLC lipid content testing that Plaintiffs claim is irrelevant and tainted to support their demands for drug product samples. Mot. at 2–3. [REDACTED]

Respectfully,

/s/ Travis Murray

Travis Murray (#6882)

cc: All Counsel of Record (via CM/ECF and electronic mail)